

REMARKS

This is in response to the Office Action mailed on August 10, 2006, in which claims 1-38 were pending. The Office Action objected to the Declaration and the Abstract. The Office Action rejected claims 1-38 as anticipated by Huebner, U.S. Pat. No. 6,030,162. With this amendment, the Abstract is shortened and claims 1, 18, 19 and 28 are amended. All of claims 1-38 are in condition for allowance, and reconsideration and notice to that effect are respectfully requested.

The Office Action found the Declaration defective, stating "It does not state that the person making the oath or declaration has reviewed and understands the contents of the specification, including the claims, as amended by any amendment specifically referred to in the oath or declaration. The oath submitted states that the person making the oath understands the application, not the specification." Applicant traverses this rejection. The original Declaration submitted by Applicant is the form promulgated by the U.S.P.T.O. for Declarations Using An Application Data Sheet, approved by the U.S.P.T.O. for use through 6/30/2006. The language which the Examiner objects to is maintained on the Declaration Using An Application Data Sheet form currently promulgated and approved by the U.S.P.T.O. Applicant believes that the Declaration form approved by the U.S.P.T.O. and currently and previously promulgated by the U.S.P.T.O. meets the U.S.P.T.O. requirements for a Declaration. This objection should be withdrawn.

The Office Action additionally found the Declaration defective, stating, "It does not identify the city and either state or foreign country of residence of each inventor. The residence information may be provided on either an application data sheet or supplemental oath or declaration." Attached hereto is a copy of the original Application Data Sheet submitted March 1, 2004 upon filing the application. The original Application Data Sheet identified the city and state of each inventor. This objection should be withdrawn.

The Office Action objected to the Abstract, stating, "The abstract is too long. It should be reduced to 150 words or less." Applicant responsively amends the Abstract to less than 150 words. The amendment is provided both showing the changes (so it can readily be seen that no new matter is added) and in clean form. The objection to the Abstract should be withdrawn.

The Office Action rejected claims 1-38 as anticipated by Huebner. Applicant respectfully traverses this rejection. In making the rejection, the Office Action combined elements from three separate embodiments of Huebner, namely, the embodiment of FIG. 14, the embodiment of FIG. 21 and the embodiment of FIG. 22. These three figures from Huebner represent separate and distinct devices. No anticipation rejection can be made based upon combining three separate and distinct devices, even if all three devices are disclosed in a single reference. Applicant respectfully submits that any rejection based on three separate and distinct devices must be based upon an obviousness analysis, including an analysis of whether a suggestion exists to combine the various features of the three devices in the way proposed in the Office Action. The Office Action includes no obviousness rejection or obviousness analysis, and the anticipation rejection should be withdrawn.

Nor would an obviousness rejection of the claims at issue based upon the three devices of FIGS. 14, 21 and 22 of Huebner be proper, concerning any of the claims at issue. For example, claim 1 requires a bone exterior section making up at least one third of a total length of the device, and requires a compression engagement on a distal end of the bone exterior section. The embodiment of Huebner FIG. 21, which the Office Action reaches to for providing the compression engagement, has a compression engagement (head 846) on a distal end of the bone exterior section, but the bone exterior section is clearly less than one third of the total length of the device. The embodiment of Huebner FIG. 22, which the Office Action reaches to for providing the bone exterior section has an intermediate section 928 and a trailing section 926, each of which make up about a third of the length of the screw, but has no compression engagement. It would not be obvious to place head 846 from Huebner FIG. 21 on a distal end of the intermediate section 928 from Huebner FIG. 22, as such placement would render the threads on the intermediate section 928 and the threads on the trailing section 926 useless. There is no teaching or suggestion in Huebner or elsewhere in the art to place head 846 from Huebner FIG. 21 on a distal end of the intermediate section 928 from Huebner FIG. 22. Huebner shows no headed device wherein the head makes up at least one third of a total length of the device. The rejection of claim 1, based upon combining head 846 from Huebner FIG. 21 with the structure of Huebner FIG. 22, should be withdrawn.

The same type of rationale can be applied to show that all of claims 1-38 are patentable over

Huebner under both an anticipation and an obviousness analysis. Claims 4 and 6, for instance, require the compression engagement to be provided by a nut rotatably supported on the threads of the bone exterior section. The head 846 of Huebner FIG. 21 clearly does not disclose or suggest a nut rotatably support on threads of the bone exterior section. FIG. 14 of Huebner shows a placement sleeve 140, which is a tool for placing the screw 110, not part of the implanted device. The placement sleeve 140 does not disclose or suggest a nut rotatably support on threads of the bone exterior section which is provided as part of the implanted device. All embodiments of Huebner use threads inside the bone fragment to hold the bone fragment in place. Nor do either head 846 of Huebner FIG. 21 or placement sleeve 140 disclose or suggest the profile required by claims 8 and 9. The portions of head 846 identified in the Office Action for “gentle slope” and “steep slope”, in particular, are on the distal side of the head 846 for insertion, not on the proximal side of the compression engagement for removal as required by claim 8 and 9. Several statements in the Office Action (Office Action, pages 5-6) about the anchor threads being self tapping proximally, about the non-engaging fragment section being substantially smooth and cylindrical, about the major and minor diameters of the fragment exterior section, and about a pointed proximal drill tip for reverse insertion are not supported by the Huebner FIG. 22 drawings.

Further, it should be noted that heading “non-engaging fragment section” identified in the Office Action on the drawing of Huebner FIG. 22 is not a section of the screw at all, but rather the minor diameter of the anchor threads. The minor diameter of the anchor threads cannot be considered a non-engaging fragment section, because the anchor threads (both major and minor diameters) engage the bone. Note that there is no leading structure which would prevent the minor diameter of the Huebner FIG. 22 anchor threads from contacting and engaging the bone. Claims 1 and 18 are amended to clarify that the various sections of the device extend longitudinally about the shaft axis, further clearly distinguishing what is meant by the “non-engaging fragment section” which is significantly different from the minor diameter of the anchor threads. Of the three devices of Huebner specified in the Office Action, only the device of FIG. 14 has a non-engaging fragment section (i.e., which fits entirely within the shadow of the anchor threads and does not engage the threads left in the bone fragment, so the bone fragment can slide longitudinally relative to the non-

engaging fragment section); however, the device of FIG. 14 is implanted entirely within the bone without a compression engagement.

The method claims of the present invention are similarly patentable over any method disclosed or suggested by Huebner. In analyzing Applicant's method claims for patentability, the issue is not whether the prior art device has the claimed structural limitation and could possibly be used in accordance with Applicant's claimed method, but rather whether the prior art reference discloses or suggests that its device actually be used in accordance with Applicant's claimed method. Claim 28, for example, requires screwing of a structure, with a bone penetration section shorter than the bone exterior section, first through the fragment and then further screwing into the anchor bone. To meet the limitations of the claim, the implant must have a bone exterior section which is longer than the bone penetration section in use after the two screwing acts. Huebner does not disclose or suggest any device which, after the two screwing acts, still has a bone exterior section which is longer than the bone penetration section.

Claim 29 requires, with the bone anchor section advanced into the bone fragment but prior to the act of further screwing the device into the anchor bone, manipulating the bone exterior section to reposition or bias the bone fragment relative to the anchor bone. The fact that a Huebner device might be able to be used in this "joystick" method of manipulating the bone fragment, is immaterial; what matters is whether Huebner disclosed or suggested such a method. In the series of Huebner FIGS. 11-14, the bone fragment is only manipulated after the device is screwed into the anchor bone. Huebner does not disclose or suggest using the device for manipulation of the bone fragment prior to screwing into the anchor bone.

Similarly, Huebner does not disclose or suggest the cutting act required in claim 37. The issue is not how the device of Huebner could be used after considering Applicant's invention, but rather what methods of use are disclosed or suggested by the Huebner reference. The rejection of Applicant's method claims should be withdrawn.

The application containing pending claims 1-38 is in condition for allowance. Reconsideration and notice to that effect is respectfully requested. The Examiner is invited to

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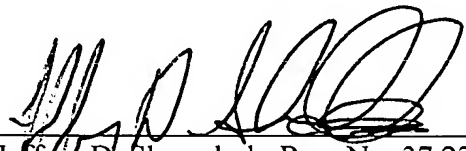
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contact the undersigned at the telephone number listed below if such a call would in any way facilitate allowance of the application.

Respectfully submitted,

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Date: November 7, 2006

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